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June 4, 2025

VIA CM/ECF

Clifton B. Cislak, Clerk of Court
U.S. Court of Appeals for the D.C. Circuit
333 Constitution Avenue, NW
Washington, DC 20001

RE: *Novartis Pharmaceuticals Corporation v. Becerra et al.*, No. 24-5235 (D.C. Cir.)

Dear Mr. Cislak:

On May 29, 2025, FDA informed MSN Pharmaceuticals, Inc., that it was converting final approval of MSN's abbreviated new drug application for sacubitril and valsartan tablets to tentative approval, consistent with the final judgment entered in the U.S. District Court for the District of Delaware ordering that the effective date of FDA's approval be no earlier than July 16, 2025. *Novartis Pharms. Corp. v. MSN Pharms. Inc., et al.*, No. 20-02930 (D. Del. Apr. 1, 2025). FDA considers the conversion to have occurred on April 1, 2025. Under tentative approval status, MSN's generic drug cannot be lawfully marketed unless and until FDA issues a final approval letter to MSN.

The Delaware case involves a patent (U.S. Patent 8,101,659) not at issue in this case that has expired but has a period of pediatric exclusivity running through July 15, 2025. The Delaware judgment thus implicates only the timing of FDA's approval. The issues in this appeal, however, involve the validity of FDA's approval—including the validity of FDA's

determination that the reference drug and MSN's generic drug contain the same active ingredients, as well as the lawfulness of FDA's approval of certain labeling carve-outs to avoid infringing patents that are set to expire in 2033 and 2036. The issues in this appeal thus remain appropriate for resolution by this Court.

Sincerely,

/s/ Caroline Tan
Caroline W. Tan

cc: Counsel of Record (via CM/ECF)